CLINICAL LABORATORY BULLETIN August 2005

Web page: http://health.utah.gov/els/labimp

❖ INTRODUCING:

Aaron Amonsen	Sample Receiving
Erin Hardin	Newborn Screening
Marc Jones	Sample Receiving
Steven Tuttle	Microbiology

NOTEWORTHY

✓ **Welcome Dr. Luedtke:** Patrick F. Luedtke, MD, MPH, was appointed Utah Public Health Laboratories Director June 1, 2005. Dr. Luedtke was State Deputy Epidemiologist prior to his appointment by Dr. Sundwall. Dr. Luedtke has a background in laboratory science having worked in clinical laboratories before attending medical school in Wisconsin. He completed an Internal Medicine Residency at Oakland Naval Hospital. He received a Masters in Public Health from the University of Utah. Dr. Luedtke will be a great asset in consulting with Public Health Professionals, Public Health agencies and the public at large. Welcome Dr. Luedtke.

✓ **Bad Preservative:** William S. Weems, MD and Patricia A. Vitale, MD, dermato-pathologists at Skin Pathology Consultants of Utah, recently completed an investigation of poorly stained slides sent to them for interpretive diagnosis. The office received more than 50 specimens from various referring physicians in which the cells stained so darkly pigmented they were difficult to interpret. An extensive quality assurance investigation determined the poorly staining slides were a result of "old" formalin.

Take home message: Dr. Weems asked us to tell facilities to be certain they rotate their formalin collection vials. Use up the old stock before starting on a new batch. If you don't collect many tissue samples, check with your reference lab for information on the vial's shelf life. Don't get bad test results from a good specimen placed in "bad" formalin.

✓ **Best Test for Respiratory Virus:** Marie Louise Landry, MD, director of clinical virology at Yale New Haven Hospital, has published many articles in the Journal of Clinical Microbiology on testing methods for the various respiratory viruses. She found:

A seven virus direct fluorescent antibody (DFA) pool as good or better than culture for detecting all viruses except adenovirus.

DFA and rapid immunoassay kits were close in sensitivity to culture on nasopharyngeal

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aspirates from children. DFA was far better than immunoassays on swabs from adults.

DFA is superior to immunoassay kits (sensitivity about 50%) for influenza A and B.

For accurate test results, match the right specimen to the right method for the right virus.

✓ **A1c Measurements with Hb Variants:** Randie R. Little, PhD, (University of Missouri School of Medicine) answered a question in the August 2005 issue of Lab Medicine about instrument variation in HbA1c (A1c) measurements. The technologist asked why there was such a discrepancy between A1c values done on the Tosoh 2.2 + (7.1%) and the Bayer ADIVA 1650 (9.9%). Could the difference be caused because the person has hemoglobin S (HbS) trait? Yes.

Dr. Little stated at least 200,000 diabetic Americans have either HbS or HbC trait. The ADVIA method/reagents is similar to the Roche Cobas Integra. Studies on the Cobas show a positive bias, higher as the A1c increases (1.5% bias at A1c of 6% and 2.7 bias at A1c of 9%). The Tosoh 2.2+ method shows no such bias.

You can check for common A1c test interferences with the National Glyco-hemoglobin Standardization Program at www.ngsp.org.

✓ **Just Add a Disclaimer to a Potassium Result for a Hemolyzed Specimen:** Frank H. Wians, Jr., PhD, MT(ASCP), DABCC, FACB pathology professor and clinical chemistry director at UT Southwestern Medical Center in Dallas said "No". He said: "Although the practice of issuing disclaimers with laboratory test results to absolve the laboratory of any responsibility for an adverse medical event if a physician who insists that his/her patient's unacceptable specimen be tested anyway, against laboratory policies and procedures, is common in many laboratories, it is inappropriate, unacceptable, and will not withstand legal scrutiny."

Dr. Wians then quoted Barbara Harty-Golder (pathologist and attorney) "There is no legally reliable way to 'unload' responsibility for an inaccurate result on the physician who asks for an unacceptable specimen to be used, in part because the patient is independently entitled to rely on the laboratory and its staff to implement appropriate safeguards for patient protection. This includes issuing only results in which the laboratory has reasonable confidence of the accuracy."

✓ **Infectious Disease Testing in Blood Units:** With the adoption of nucleic acid-amplification testing (NAT) in 1999 the residual risk of getting HIV-1 or HCV from a blood transfusion decreased to 1 in 2,000,000. The next step was to find a cheaper, faster way to test donors. Minipools seem to be the answer. Gen-Probe's Transcription-mediated Amplification system can screen a pool of 16 donors and Roche's Molecular Systems Cobas AmpliScreen HIV-1 and HCV can screen a pool of 24 donors. It seems NAT testing is better at detecting infection during the window period than HIV-1 p24 antigen testing.

✓ **My CBC Results Must Be OK, My Controls Were In:** Tim R. Randolph, M.S., MT(ASCP), CLS(NCA) wrote about an easy way to check patient accuracy with your complete blood count (CBC) analyzer. The old hematology H & H rule is still valid. The Hb (hemoglobin) x 3 = Hct (hematocrit) ± 3%. Likewise the MCHC rule is a good quality assurance check. The MCHC should be below the upper limit of the normal range (usually < 36 g/dL). These two rules applied to patient results can boost your confidence in your instrument or point out problems before you fail proficiency testing.

Mr. Randolph said most CBC analyzers calculate the red blood cell concentration. So when the H & H rule fails, there may be an electrical impedance problem (if the instrument draws from the RBC bath) or a hemoglobinometry problem (if the instrument draws from the white blood cell [WBC] bath).

Mr. Randolph states "The four most common issues that adversely affect the Hbg measurement are lipemia, high WBC count, Hbg S &/or C, and hypergammaglobulinemia."

Don't rely solely on being in the acceptable published control range. Often the first complaint about proficiency test failures is "My controls were in, how could I fail?"

✓ **Blood Substitute Trials:** The FDA granted Northfield Laboratories (Evanston, IL) a "no-consent" study permit for its new blood substitute – PolyHeme. FDA has approved 15 other such studies. Paramedics are testing the product on severely injured patients who are unable to respond to consent questions. Local meetings are held at the study sites. Any person who does not want the blood substitute is given a special bracelet to wear during the study period. Testing and proposed sites include Loyola University Medical Center; Mayo Clinic; Memphis Regional Medical Center; and Huston Texas Medical School.

✓ **OSHA Phlebotomy Advisory:** Many health care facilities are unaware of the OSHA Safety and Health Information Bulletin published October 15, 2003 titled "Disposal of Contaminated Needles and Blood Tube Holders Used for Phlebotomy". While not regulation, the advisory is designed to help phlebotomists work more safely in a dangerous environment. The acronym "SESIP" in the document stands for Sharp with Engineered Sharps Injury Protection.

"Prevention of needlestick injuries during disposal of sharps, following phlebotomy procedures, depends on immediate disposal of the blood tube holder unit, with SESIP attached, and as a single unit after each patient's blood is drawn."

So toss that vaccutainer holder with the needle. You may need a bigger hard wall sharps container. To read the entire bulletin, go to www.osha.gov.

✓ **HCV Confirmation Testing:** There are many plans by reference laboratories as to which confirmation test is best for a positive hepatitis C virus (HCV) antibody screen. Urine screening tests have complicated the picture even more. Nancy Cornish, MD, directing microbiology at Omaha's Methodist Hospital and Children's Hospital recommends a protocol based on the S/CO ratio. She published her protocol in the April, 2005 issue of CAP Today. Low screening test results require a recombinant immunoblot assay (RIBA). High screening test results have PCR confirmation and may at some point go the RIBA testing also. Utah's ARUP is preparing their algorithm to be in line with CDC's recommendations. Consult with your reference lab to see if they meet CDC's suggestions.

FROM THE PATIENT'S CHART

"Rectal examination revealed a normal size thyroid."

☆ Feature ☆

COMPETENT: YES OR NO

Oh, those annual employee competency checks (every six months for new employees), not again! Do you find yourself waiting until the lab inspector has scheduled a survey before you do them? Do you simply sign a paper saying everyone is competent since they come to work on time every day and finish the work before they go home?

No single checking method can guarantee the competency of all employees in all laboratory situations. CLIA and accrediting agencies require technical supervisors to check, at a minimum, their employee's ability to perform and report tests accurately, timely and proficiently. The method(s) chosen must include direct observation (all aspects of testing including instrument maintenance and function checks), monitoring reports, reviewing all paperwork, assessing test performance on unknowns (proficiency testing, blind samples, repeat tests, etc.), and checking problem solving skills.

How can you do all these things for each test for each employee each year? Jennifer Schiffgens, MBA, MT(ASCP) and Valerie Bush, PhD, MT(ASCP) discussed that question in an article for the August, 2001 issue of Laboratory Medicine. The article, "A Four-Part Approach to Competency Assessment" had some excellent points.

The authors warn don't just check daily work (test results, proficiency tests, quality control) and use written exams. These steps are great for determining technical competency, but may not identify pre-analytic or problem solving issues. Your lab may be operating fine as a whole, but each individual must be rated separately to find specific problems that may require process change or additional training.

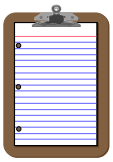
The authors suggest you investigate the process when you find competency problems. The correction usually lies with process adjustments, not people adjustments. CLIA surveyors seldom find "re-training" employees correct laboratory problems. Don't threaten or punish employees until you are certain the process is flawless (including the training and understanding piece). "The laboratory does not reprimand the liquid controls when they are out of range or terminate a procedure when there is a typographic error." Work backwards from the problem to the source (root cause). Don't assume most problems are from "bad" employees or from "good" employees having a bad day. Sometimes this is true, but not as often as sited for a cure.

If part of your evaluation is a written exam, change the questions each year. Have at least 5 answers for multiple choice questions (this helps differentiate the good guessers from the knowledgeable employee). Don't make all questions in the same format (true/false or multiple choice).

Don't forget direct observation. Set up a practical exam situation. One Utah facility chain had an annual competency event for all employees. They set up different stations with short written quizzes, hands-on testing for obersvation, and problem solving situations with a live person to talk them through the correct solutions. Then, food!

Remember the follow up part to any quality assurance activity. Make certain process changes are implemented. Reevaluate employees after training sessions to make certain they understand what was taught. Make continuous quality improvement the natural "culture" in your laboratory and more work can be done with fewer frustrated employees.

Future bulletins will discuss some specific competency methods.



CLIA BITS

ADDITIONAL WAIVED TESTS:

° Metrika Inview Multi-Test A1C

° ACON Laboratories On Call Multi-Drug Home Test Cup; FSH One Step Menopause Test Strip and Test Device

° Redi-Test Cassette Multi-Drug, Multi-Line Screen Test Device for drugs of abuse

° iCassette Multi-Drug, Multi Line Screen Test Device for drugs of abuse

° Branan Medical Corporation ToxCup Drug Screen Cup

° Stanbio HemoPoint H2 Hemolglobin Measurement System

° Arkray SPOTCHEM EZ Chemistry Analyzer for SGPT (ALT) and glucose

° Biomedix Inc. Q Steps Biometer G/C Dual Monitoring System for cholesterol and glucose

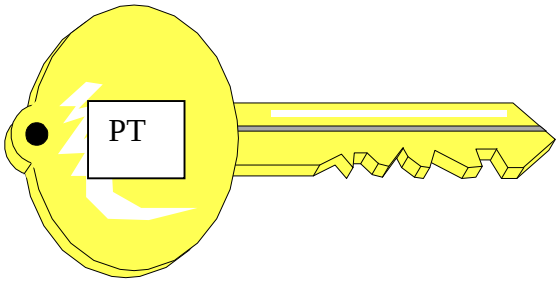
° Abaxis Piccolo Point of Care Chemistry Analyzer (Lipid Panel Reagent Disc – Whole Blood) for SGPT (ALT) and SGOT (AST)

° Roche Diagnostics Accuchek Instant Plus Dual Testing System for cholesterol & glucose

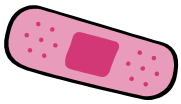
° Biosite Triage Meter and Meter Plus (whole blood) for B-type natriuretic peptide (BNP)

Equals

"100 rations = 1 C-ration"



The College of American Pathologists (CAP) met with representatives from CDC the end of March. CDC told CAP they expect a subcommittee from The Clinical Laboratory Improvement Advisory Committee (CLIAC) to review the cytology proficiency testing grading criteria and make recommendations to CLIA. CAP is lobbying for grading reform and updating the PAP smear nomenclature.



SAFETY

Daveda Holmberg, MT(ASCP) of Circle Pines, MN wrote an article for October, 2005 Lab Medicine entitled "Laboratory Waste Legal Issues". The author's hospital must treat waste with >1% hazardous chemicals as hazardous waste. Getting this information from manufacturers has been difficult. Manufacturer's formulas are often proprietary. Manufacturer's MSDS tell the laboratory to check with their local pollution agencies for disposal instructions. The agencies ask the lab

exactly what is in the reagent. The lab is caught in a whirlpool.

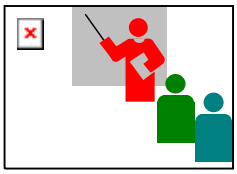
The author's lab neutralizes corrosive reagents before sending them into the sewer after asking the manufacturer if it is safe to do so. The lab found 2,4,5 trichlorophenol in a stain rinse they use. This chemical must go to Canada to be destroyed!

Work with your reagent manufacturer's and local sewer district to find out how to dispose of your laboratory waste properly before your facility is fined.

"Once you have accepted yourself, it's so much easier to accept other people and their point of view."

Unknown

CONTINUING EDUCATION



National Laboratory Training Network (NLTN) & Alabama Department of Health

2005-2006 Antimicrobial Susceptibility Testing Web Conference. This four part series will be November 8, 2005; December 6, 2005; January 17, 2006 and February 7, 2006. Janet Hindler, MCLS, MT(ASCP), F(AAM), senior Specialist in Clinical Microbiology for the UCLA Medical Center's Division of Laboratory Medicine will present the four 1.5 hours conferences. The sessions are $50 each or $150 for all four. For registration information call 800-536-NLTN or e-mail seoffice@nltn.org.

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NLTN Needs Assessment

The NLTN is requesting anyone interested in a hands-on *Molecular Diagnostic Parasitology* workshop targeted to public health and clinical laboratory scientists to respond to a short needs assessment survey at http://www.surveymonkey.com/s.asp?u=983221330519.

The workshop would be held next spring at the Washington State Public Health Laboratory for 2.5 days. The exercises could cover detection of Cyclospora, Cryptosporidium, Malaria, Microsporidia, Babesia or *E. Histolytica / E. dispar* by PCR in clinical specimens and food (as need dictates).

"Every undertaking looks like a failure in the middle."

Rosabeth Moss Kanter